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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/181,585	10/28/98	RANUM L	110.00900101

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EXAMINER	
SOUAYA,J	
ART UNIT	PAPER NUMBER
1655	17

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/181,585	Ranum et al
Examiner	**Art Unit**
Jehanne Souaya	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 6, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4, 7-19, and 21-52* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *2-4, 8, 10, 13, 15-19, 37, 40, 43-49, and 52* is/are allowed.

6) ☒ Claim(s) *1, 7, 9, 11, 12, 14, 21-36, 38, 39, 41, 42, 50, and 51* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Currently, claims 1-4, 7-19, and 21-52 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 112

Written Description

3. Claims 1, 7, 9, 11-12, 14, 21-36, 38, 39, 41-42, and 50-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification teaches that the ataxias are a clinically and genetically heterogenous group of neurodegenerative disease that are characterized by trinucleotide repeat expansions, the

largest group being that of CAG expansions that are translated into polyglutamine tracts (see p. 1, para. 2). The specification also teaches that in general, a high number of CAG repeats in a particular SCA coding sequence indicates that an individual is suffering from spinocerebellar ataxia, or may develop symptoms in the future, and that the number of CAG repeats that is indicative of spinocerebellar ataxia typically varies with the type of SCA (see p. 2, lines 26-30). The specification teaches that an SCA8 allele with less than 80 CTG repeats is normal, and that an SCA8 allele with less than 91, preferably less than 33 combined CTG and CTA repeats is normal (see p 13, lines 14-23).

The recitation of "SCA8 coding sequence" encompasses the SCA 8 gene, and the SCA8 cDNA sequence which have not been taught in the specification. The recitation also reads on the full length ORF of SCA8, which does not appear to be taught in the specification. The specification defines "coding sequence" to refer to a nucleotide sequence that codes for an mRNA that may or may not be translated into protein. Such a definition reads on a gene as well as a full length ORF. With regard to the SCA8 gene, the specification does not define the gene sequence where the SCA8 allele is located. With regard to the SCA8 full length ORF, the specification has only taught a single sequence which is found at the SCA8 allele, SEQ ID NO 1, however, it is unclear if this sequence corresponds to a full length open reading frame as the specification also teaches that the product of the SCA8 mRNA is never encoded into a protein. On page 12, the specification defines SEQ ID NO 1 as genomic DNA that includes the repeat region of SCA8. However a gene includes introns, exons, and regulatory sequences that have not been taught in

the specification. The specification has only taught (p 26) that a 1.2 kB insert that contains the CTG expansion and flanking genomic DNA was sequenced. The specification does not teach the full sequence, nor does the specification teach whether this insert contained the full length open reading frame of SCA8 or the SCA8 gene. The specification further defines SEQ ID NO 2 as mRNA of the SCA8 coding sequence that contains exons D,C,B, and A. SEQ ID NOS 3 is also defined as mRNA of the SCA8 coding sequence, but SEQ ID NO 3 contains exons E,C,and A. Thus it is unclear what the full length open reading frame of SCA8 is composed of, that is, are SEQ ID NOS 2 and 3 alternative splice variants, or do they only represent partial sequences. Furthermore, if the SCA8 gene is never encoded into a protein, it is unclear whether additional sequences also comprise the presumed cDNA sequence of SCA8, that is there may be additional exons that are not described in the specification. As the specification does not describe the complete SCA8 region, but only teaches specific SEQ ID NOS that are found within the region, the specification fails to describe a representative number of sequences that are encompassed by the "comprising" language and the "coding sequence" language found in the claims.

With regard to claims 33 and 34, the claims read on sequences that only need have 15 nucleotides from the designated nucleic acid sequences of SEQ ID NO 1. The term "consisting essential of" is considered open language, as the full cDNA sequence of SCA8 has not been taught in the specification and it is unclear what the claim or the specification considers "essential" to the isolated oligonucleotide sequence claimed. That is, the claim reads on any sequence that contains only 15 nucleotides from SEQ ID NO 1 and any number of nucleotides on either side.

Such nucleotides could bear little resemblance to the nucleic acid sequence of SEQ ID NO 1. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify polynucleotides that constitute probes or primers to SCA8 other than those defined by SEQ ID NO. The term "SCA8" is not art recognized other than such a term refers to a particular SCA allele. The term does not make clear the sequence of either the full length ORF of SCA8 or the SCA8 gene, and thus the prior art is silent with respect to structural and functional features that may be used to identify such polynucleotides.

Each of the claimed inventions is a genus for which a representative number of sequences for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set for the by the Court in *Vas Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of SCA8 gene, ORF, coding sequences, or sequences "comprising, the specification fails to show that applicant was in fact "in possession of the claimed invention" (with regard to the broad scope of the claims), at the time the application for patent was filed.

Response to Arguments

The response traverses that as defined in the specification, a coding sequence includes the nucleotides that code for an mRNA and does not include regulatory regions, including for

instance a promoter. This argument has been thoroughly reviewed but was found unpersuasive as the definition in the specification could be read to mean that the coding sequence codes for an mRNA, wherein the mRNA may or may not be translated into a polypeptide when placed under the control of appropriate regulatory sequences. The recitation in the specification does not appear to exclude appropriate regulatory sequences from the 'coding sequences'. Furthermore, the term "coding sequence" also reads on the full cDNA sequence of SCA8, which has not been taught in the specification (see explanation above as to why it is unclear from the recitation in the specification as to whether SEQ ID NOS 1, 2, or 3, or all 3 sequences represent the full cDNA or open reading frame of SCA8. The specification does not define what the full length cDNA sequence of SCA8 is. The rejection under 35 USC 112, first paragraph made in the previous office raised this point on page 6 and page 8, last paragraph prior to "Conclusion").

The response further traverses that the recitation of hybridization conditions in the claims provides a precise definition that distinguishes the claimed subject matter from other materials and that the species disclosed is representative of the genus because all members must have a nucleotide sequence which hybridizes under the recited conditions. This argument has been thoroughly reviewed but was found unpersuasive because the recitation of "...SCA8 coding sequence 'comprises' a nucleotide sequence, the complement of which hybridizes to the nucleotide sequence set forth at SEQ ID NO 1..." reads on sequences larger than SEQ ID NO 1, which can include the full length cDNA of SCA8, the gene sequence, as well as sequences on

either side of SEQ ID NO 1, which will hybridize to SEQ ID NO 1 under the recited conditions and which have not been taught in the specification.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Jehanne Souaya
Patent examiner
October 18, 2001